UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,990	11/21/2003	Horst Heirler	028622-0125	8166

22428 7590 11/20/2006

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/717,990	**Applicant(s)** HEIRLER, HORST	
	Examiner Leslie A. Royds	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-6 and 8-19*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Leslie A. Royds
Patent Examiner
Art Unit 1614

13 Nov 06

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's proposed after-final submitted 27 October 2006 presents arguments directed to the rejection set forth under 35 U.S.C. 103(a). Specifically, Applicant states that, "Bell merely discloses a diabetic supplement bar containing a particular amount of simple carbohydrates for the treatment or prevention of nighttime hypoglycemia in a diabetic patient. By contrast, claim 1 of the present claim set relates to a completely different method, namely a method for supplementing the diet of a subject with diabetes mellitus comprising administering to the subject medium-chain triglycerides or a composition comprising medium-chain triglycerides in an amount sufficient to regulate or normalize fat metabolism in the subject. This amount of the medium-chain triglycerides is defined as being 10-30%...On page 2 of Bell, lines 31-33, it is merely stated that the diabetic supplement bat should further include about 2-30% by weight lipid." Applicant further states that Bell does not teach the other aspects of present claim 1 and that one skilled in the art had no incentive to combine Bell with, for example, Zawistowski because the subject matter of Zawistowski completely differs from that of Bell.

Applicant does not present any amendments to the claims in the after-final amendment of 27 October 2006.

Regarding Applicant's argument that Bell is directed to a completely different method than that presently claimed, it is noted that the presently claimed method is directed to a method for supplementing the diet of a subject with diabetes mellitus comprising the administration to the subject medium-chain triglycerides or a composition comprising medium-chain triglycerides in an amount sufficient to regulate and normalize fat metabolism in the subject, i.e., 10-30% medium chain triglycerides. Though Bell is directed to the regulation of night-time hypoglycemia in a diabetic patient, the required therapeutic objective and step is met by the reference for the following reasons: (1) the subject of Bell would have necessarily consumed a diet of food and, therefore, the consumption of the diabetic supplement bar of Bell would have necessarily been a "supplement" to the regular diet of the diabetic patient and, therefore, meets the claimed objective of "supplementing the diet of a subject with diabetes mellitus" (see present claim 1); (2) the host of Bell is the same as that presently claimed, i.e., a diabetic patient; (3) the diabetic supplement bar of Bell contains a lipid component comprised of medium-chain triglycerides and long-chain triglycerides in an amount of 2-40% by weight of the bar; and (4) the fact that Bell teaches a lipid component in the amount of 2-40%, which is comprised of both medium-chain triglycerides and long-chain triglycerides, clearly contemplates embodiments wherein the total percent by weight of medium-chain triglycerides is 10-30% and the remainder of the 2-40% total lipid fraction is comprised of long-chain triglycerides. For example, to comprise a lipid fraction of 40% by weight of the composition, the medium chain triglyceride component may be present in an amount of 30% and the long chain triglyceride component may be present in an amount of 10%. Although Applicant appears to be asserting that the difference between Bell and the presently claimed method is that the amount of Bell is not sufficient to regulate or normalize fat metabolism in the subject (see page 8 of Applicant's remarks), the fact that Bell teaches amounts of the lipid fraction of the diabetic supplement bar that overlap with those presently claimed clearly demonstrates that the function that Applicant has attributed to the presently claimed amount of medium-chain triglycerides must necessarily be present. Different properties cannot be attributed to identical quantities of an identical chemical component administered under the same circumstances or, in the present case, the same host. Please see MPEP Sect. 2112.

Furthermore, even if Applicant were correct in asserting that Bell fails to teach the medium chain triglycerides in an amount of 10-30% by weight of the composition, Applicant has failed to address the reasoning provided in the previous Office Action as to why the determination of such an amount would have been within the routine skill of the artisan. Furthermore, Applicant has made no attempt to demonstrate that the particularly claimed amounts are critical to the invention. In other words, should Applicant rely upon the fact that a particular amount is critical to the invention, Applicant must make an objective showing that at least a representative showing of results over the claimed range achieves unexpected results relative to the prior art range [In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)] and that the unexpected results demonstrated over this range demonstrate a marked improvement over that achieved using the amounts of the prior art such that the difference shown is actually a difference in kind and not just a difference in degree [In re Waymouth, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974)].

Applicant again argues that the reference to Zawistowski completely differs from that of Bell and, therefore, one of skill in the art would not have been motivated to combine Bell with Zawistowski. However, Applicant's argument that the cited reference to Zawistowski et al. is non-analogous art and, therefore, should not be combined with Bell as in the instant rejection is not persuasive. While the references may be directed to differing art, clearly both of the cited references are directed to resolving the same problem of dietary and nutritional supplementation and special nutritional requirements of diabetic patients. Those skilled in the art would have been expected to consider those areas of art that have similar problems in seeking a solution. The skilled artisan would necessarily have considered the prior art generally available at the time of the invention regarding known nutritional and dietary requirements of diabetic patients and, thus, the cited art is properly considered relevant and would have naturally commended itself to the attention of one of ordinary skill in the art.

This conclusion is supported by the MPEP at §2141.01(a)[R-2], which states, "The Examiner must determine what is 'analogous prior art' for the purpose of analyzing the obviousness of the subject matter at issue. 'In order to rely on a reference as a basis for rejection of an Applicant's invention, the reference must either be in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned.' ... 'A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." (emphasis added)

Lastly, regarding Applicant's continued assertions that the primary reference to Bell and the cited secondary references to, e.g., Zawistowski et al., do not teach the entirety of the presently claimed invention, Applicant is reminded that the rejections made under 35 U.S.C. 103(a) are based upon the combination of references. Applicant clearly does not address the combined teachings as a whole, but rather focuses solely on the discrete teachings of each of the cited references and asserts that, since no single reference teaches the

presently claimed invention in its entirety, that the rejection is improper. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. Please reference In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, rejections under 35 U.S.C. 103(a) are based upon combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one of ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were prima facie obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather the test in what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please see also In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Accordingly, Applicant's remarks presented in the after-final submission of 27 October 2006, will be entered into the record, but are not persuasive for the reasons described supra and further relying upon those previously set forth in the final rejection. Reconsideration of the present application has been performed, but the rejections of record are maintained.

13NOV06

Ardin H. Marschel 11/13/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER